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ZARGIS MEDICAL

Summary of Safety and Effectiveness

Special 510(k) Premarket Notification – ZAC Energy and Timing Display

CLASSIFICATION NAME:	Phonocardiograph with Waveform Analysis 21CFR 870.2390 This device is categorized as DQC It is regulated as Class II
COMMON/USUAL NAME:	Heart Sound Analyzer
TRADE NAME:	Zargis Acoustic Cardioscan (ZAC)
MANUFACTURER	Zargis Medical Corp. 755 College Road East Princeton, NJ 08540
MANUFACTURING LOCATION	Zargis Medical Corp. 755 College Road East Princeton, NJ 08540
ESTABLISHMENT No.	FDA Form 2891 Submitted

PERFORMANCE STANDARDS:

The device complies or will comply with the relevant international and national Safety Standards. It has been manufactured in compliance with the Quality System Regulation.

SYSTEM DESCRIPTION:

The ZAC is a computer-assisted auscultatory device, intended to provide support to the target users in the evaluation of heart sounds and murmurs. The product will acquire and record the acoustic signal of the heart, over appropriate regions of the chest, and then analyze these signals. The analysis procedure will evaluate sounds of the heart and aid healthcare providers in identifying murmurs. Results are presented to the user in near real-time.

As a complete system, the ZAC consists of an electronic stethoscope, a laptop computer, software, and a printer.

The ZAC system was cleared by FDA on 26 May 2004. The proposed revisions, included as part of this submission, do not affect the current method of operation, data acquisition, processing, or existing data analysis in any way.

Zargis wishes to submit, for FDA review, a revision to the previously cleared ZAC system. The proposed changes to the system:

1. Add, to the existing user interface, a graphical display of timing and energy of any suspected murmurs that may have been identified.
2. Revise the existing Heart Sound Recording Display to remove the "mm" label from shaded areas designating the location of suspected murmurs
3. The wording of the summary reports returned when suspected murmurs identified have been changed to include a designation of the heartbeat interval in which the suspected murmur occurs
4. Minor software revisions to correct or adjust operational anomalies identified since the previous submission
    a. Adjusted sequence of software routine calls to shorten analysis time
    b. Store software revision level as part of patient record
    c. Have software license expire annually
    d. For increased security, disable Windows shortcut keys
    e. For increased security, disable Ethernet card and jump drive

EQUIVALENCE INFORMATION:

Zargis wishes to receive FDA clearance to market this revised product based on its substantial equivalence to the original device cleared by FDA. There are no changes in intended use of the product, nor any changes in technology. The previously cleared system included a graphical display of the heart sound and graphically highlighted the suspected murmur. The new display will identify in which of 4 time periods (subdivisions of the cardiac waveform) the suspected murmur occurs and provides a metric that establishes the onset and duration timing of the suspected murmur. The graphical display also presents, in histogram format, the sound energy during each time period. The revised graphical representation allows an increased level of quantification of the display.

SAFETY INFORMATION:

The results of the hazard analysis, combined with the appropriate preventive measures taken indicate the change to the ZAC, as the ZAC itself, is of minor level of concern, per the August 29, 1991 issue of the "*Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review*".

The ZAC device continues to have no patient contacting materials and is utilized only by trained professionals. As it was for the original ZAC, the output of the improved device is evaluated by trained professionals allowing sufficient review to afford identification and intervention in the event of a malfunction. Device output and analysis is used to indicate the appropriateness of a referral. The device impacts the quality or status of the original acquired data only in the validated manner described.

Zargis feels that sufficient information and data are contained in this submission to enable CDRH to reach a determination of substantial equivalence within a reasonable time period. In the event that additional information is required, please contact Zargis Medical Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Zargis Medical Corporation
c/o Mr. Donald Brooks
Vice President, Operations
755 College Rd. East
Princeton, NJ 08540

Re: K042128
Trade Name: Zargis Acoustic CardioScan (ZAC)
Regulation Number: 21 CFR 870.1875, 870.2390
Regulation Name: Stethoscope, Phonocardiograph
Regulatory Class: Class II (two)
Product Code: DQD, DQC
Dated: August 4, 2004
Received: August 6, 2004

Dear Mr. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

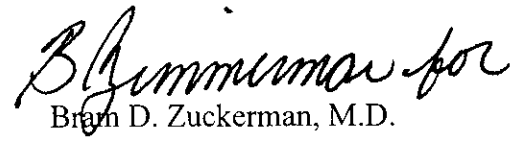
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042128

Device Name: Zargis Acoustic Cardioscan (ZAC)

Indications for Use:

The Zargis Acoustic Cardioscan, (ZAC), is an electronic auscultatory device, intended to provide support to the physician in the evaluation of heart sounds in patients.

The product will acquire and record the acoustic signals of the heart and analyze these signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs.

The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.

The interpretations of heart sounds offered by the Zargis Acoustic Cardioscan are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

Over the Counter Use _____

510(k) Number K042128